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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,174	06/08/2006	Keiichi Fujiwara	0020-5490PUS1	8923

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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08/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/582,174	Applicant(s) FUJIWARA ET AL.	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-11 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-11 and 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The response filed June 10, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claims 1 and 20 have been amended.
2. Claims 1, 4, 6-11, 13-23 are pending in the case.
3. Claims 1, 4, 6-11, 13-23 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4, 6-11, 13-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims recite an intended use comparison in regards to techniques such as coating and microcapsulation. While the recitation has no patentable weight on the claimed components of the composition as there is no material recitation affecting the composition components, this amendment is

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new matter as the disclosure does not address the negative comparative for coating or microcapsulation techniques and also does not describe what microcapsulation forms are encompassed as the dependent claims recite granules and fine granules. There is no support in the disclosure for the amendment and this is a new matter rejection.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 1, 4, 6-7, 11, 13-20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625).

It is noted that the new amended recitation of the claims appear to be directed to an intended use comparison which has no patentable weight on the claimed components of the composition as there is no material recitation affecting the composition components. The art rejection below addresses the component limitations of the composition.

Siebert et al. teaches an oral disintegrable dosage form comprising an active ingredient, sugar or sugar alcohol, binders, disintegrants, and other excipients. The dosage form can be a tablets and capsules. They can also be a microgranule, granules, particles, and microparticles; wherein these forms are collectively termed "microcapsules" in the teaching and Siebert also teaches that all these forms need not be coated at all (Col. line 39-50). Siebert also teaches powders which can be coated or

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uncoated (Col.4 line 47-68). The active include pharmaceutical ingredients and the formulation is particularly capable of taste masking distasteful drug particles. The sugar or sugar alcohol preferably includes mannitol. The binders preferably include microcrystalline cellulose, starch, and methyl cellulose. Desirable disintegrants include crospovidone. Example 1 is a powder (granular) composition comprising famotidine, mannitol, microcrystalline cellulose (Avicel), and crospovidone that is formed into a tablet. The ratios for famotidine, mannitol, and binder are based on the amounts of each component. The amount of water is negligible as it is evaporated during granulation. There is 9.09mg of famotidine, 30mg microcrystalline cellulose, and 151.1mg mannitol in the tablet. The ratio of famotidine to the binder is 9.09:30 or 1:3.3. The ratio of binder to mannitol is 30:151.1 or 1:5.04.

The disintegration properties and profiles are intrinsic to the composition. When the components of compositions are met, the properties related to it are the same. The composition is prepared by creating a coating solution (water-containing solvent comprising ethyl cellulose and HPMC-both binders), the drug (famotidine), is screened, coated while granulated, blending with mannitol, binder, disintegrant, other excipients, screened, mixed, powder is discharged, then tableted (see full document, Abstract, Col. 2 line 13-Col. 4 line 58, Col. 5 line 1-48, Col. 6 line 46-63, Col. 7 line 7-50, Example 1).

Siebert et al. does not expressly teach methylcellulose in the example or an example of a granule form of the composition.

However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute methylcellulose for microcrystalline

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cellulose, as suggested by Siebert, and produce the instant invention. Siebert teaches that the preferred binders include microcrystalline cellulose and methyl cellulose. It would have been obvious to one of skill in the art to substitute one preferred binder for another depending on availability or desired properties as they are taught to be analogous. It is also obvious to form granules as taught by Siebert (forms taught include granules, particles, microparticles, powder, tablets) with the formulations presented such as in Example 1 by granulation with the same granulation process taught by Siebert in Example 1 with the same aqueous solvent presented (water with binders), as it is within the skill of one in the art and these minor variations are routinely practiced in the art to determine the best therapeutic efficacy and profile for the best outcome in the final product.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have analogous choices to substitute the binders when motivated by pricing, availability, or desired properties of the binder used to produce the final product. It is also desirable to have different forms of the same product for different modes of delivery dependent on the profile desired.

1. Claims 8-10, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625) as applied to claims 1, 4, 6-7, 11, 13-20, 22-23 above, in view of Depui et al. (U.S. Pat. No. 6132771) and further in view of Yoshinari et al. (U.S. Pat. No. 6235947).

The teachings of Siebert et al. are addressed above.

Siebert et al. does not expressly teach the incorporation of D-mannitol or mosapride (4-amino-5-chloro-2-ethoxy-N—[[4-(4-fluorobenzyl)-2-morpholinyl]-methyl]benzamide) or a commercial package.

Depui et al. teaches the usefulness and incorporation of mosapride for the treatment of gastro oesophageal reflux disease (GORD, also known as GERD). Depui also teaches that famotidine is known to be used for GORD/GERD (Abstract, Col.1, lines 20-33, 50-65, Col.2, lines 2-4, Col. 7, lines 55-68, Col. 8, lines 1-5, Examples).

Yoshinari et al. teaches that D-mannitol is of high value as an excipient for high moisture sensitivity as it is not hygroscopic and retains no substantial moisture. The D-mannitol produced has excellent compressibility and has versatility as it can be used for direct compression, wet-granulation, or dry-granulation. It can be used as a good excipient for pharmaceutical compounds (Abstract, Col. 1, lines 10-17, Col.4, lines 19-50, Col.8, lines 1-20).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute mosapride for famotidine and D-mannitol for mannitol, as suggested by Depui and Yoshinari, and produce the instant invention. Mosapride and famotidine as both used for GORD as taught by Depui, known to have unpleasant tastes (see Siebert above and Yoshioka et al. (WO 2004/066913), pages 2-3), so it would have been obvious to one of skill in the art to substitute mosapride for famotidine as it is routine to use known formulations for analogous drugs, with a reasonable expectation of success. As the composition of Siebert is disintegrable, and

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thereby sensitive to humidity, it would be obvious to substitute the mannitol with D-mannitol as Yoshinari teaches that D-mannitol is desirable as an excipient for high moisture sensitivity formulations as it is not hygroscopic and retains no substantial moisture. It is noted that when the components of the composition are met, the properties intrinsic to the composition are met.

It is also obvious to place any composition in a package to not only designate what the composition is through labeling, but also for storage, shipping, and stability to stores, pharmacies, and consumers. Written matter for the use of a known drug (mosapride), particularly for an existing use, does not impart patentability. An example of this is a disintegrating tablet formulation of mosapride in a Press Through Pack package disclosed in Shirai et al. (U.S. Pat. No. 6413541, Col. 2, lines 55-65) or packaging of Yoshioka et al.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to optimize the same formulation for analogous drugs to reduce the amount of experimentation, research, and development to lower cost and improve efficiency. It is also desirable to use similar and analogous drugs for the same purpose for composition formulation when motivated by pricing, availability, or desired properties of the final product. It is also desirable for manufacturers place any composition in a package to maintain stability (humidity-desiccants), reduce breakage, and increase ease of storage and shipping to stores, pharmacies, and consumers. Thereby reducing production costs (less breakage and spoilage) and improving

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acceptable of consumers and distributors. Written matter for the composition, is desirable for manufacturers to ensure that the composition is taken appropriately.

Response to Arguments

10. Claim 1, 4, 6-7, 11, 13-20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625).

Applicant's arguments filed 6/10/2009 have been fully considered but they are not persuasive. Applicant's arguments are directed to the assertion that the claim recites particles that are not coated, that the declaration of Dr. Shimono is evidence that the composition are unexpectedly effective at taste masking, and that one of skill in the art would not substitute methylcellulose for microcrystalline cellulose. This is not persuasive as Applicant's arguments are not commensurate in scope with the claims. As addressed above, the new amended recitation as written is directed to an intended use comparison which has no patentable weight on the claimed components of the composition as there is no material recitation affecting the composition components. The art rejection above addresses the component limitations of the composition. Additionally, Siebert does address the particle and powder form and teaches that they do not need to be coated. Siebert teaches several forms including a microgranule, granules, particles, and microparticles; wherein these forms are defined to be collectively termed "microcapsules" in Siebert and apply to the instant claims including those to granules and fine granules. The amendment which is subject to the new matter above, does not address in the disclosure as to what forms are encompassed by the term.

As for the declaration, it has been fully considered but is not persuasive. It is not commensurate in scope with the claims, the comparative is not persuasive as both formulations showed taste masking properties and a demonstration of improved taste masking is not unexpected as Siebert teaches that the formulation is for taste-masking and that methylcellulose and microcrystalline cellulose are functional equivalents that are binders and methylcellulose is preferred wherein it is obvious to substitute one functionally equivalent for another. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

Accordingly, the rejection is maintained.

2. Claims 8-10, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625) as applied to claims 1, 4, 6-7, 11, 13-20, 22-23 above, in view of Depui et al. (U.S. Pat. No. 6132771) and further in view of Yoshinari et al. (U.S. Pat. No. 6235947).

Applicant's arguments filed 6/10/2009 have been fully considered but they are not persuasive. Applicant's arguments are directed to the assertion that Siebert does not teach the particles, unexpected results, the composition with the particles and additional components, methylcellulose in a granule form. This is not persuasive as the argument in regards to Siebert for the particles are addressed above, the arguments for unexpected results are addressed above, the composition with the components of the composition are addressed in the art rejection as a prima facie case for the combination is addressed above, and the assertion of methylcellulose in a granule form is unclear as

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there is no claim recitation for this limitation. The rejection was directed to Siebert et al. not expressly teaching methylcellulose in the example or an example of a granule form of the composition.

Accordingly, the rejection is maintained.

Conclusion

11. Claims 1, 4, 6-11, 13-23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Zohreh A Fay/
Primary Examiner, Art Unit 1612